K001044

NOV - 3 2000

510(k)
Summary of Safety and Effectiveness

3/16/00

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

Company Name/Contact:

Acme Spine, LLC.
9980 Indiana Ave Unit 9
Riverside, CA 92503
Ph: (909) 352-9862
Fax: (909) 352-9861
Regulatory Affairs, Tim Williams

Device Name:

Trade Name: ACME SPINE SYSTEM

Common Name: Spinal Fixation System

Classification Names:

Spondylolisthesis Spinal Fixation Device System
Pedicle Screw Spinal System

Establishment Registration: Pending

Classification:

The Orthopedic and Rehabilitation Device Panel assigned the unique device Classification codes MNH and MNI (Class II) to this device system. The published Physical description of these devices is in 21 CFR, 888.3070. These Devices are classified as Class II medical devices.

Performance Standards:

No applicable Food and Drug Administration mandated performance standards for this device exist. Voluntary standards utilized in regards to this device include: ASTM F1717 (Test methods for spinal implant constructs), FDA Guidance for Spinal System 510(k)'s May 7, 1999, ISO and ASTM material standards and FDA Quality Systems Regulations And CGMP regulations.

Device Description:

The Acme Spine System consists of finished, single use, monoaxial and polyaxial pedicle screws, locking plugs, spinal rods and rod to rod connectors. The components come in a variety of sizes which allow a construct to be built to stabilize the spine and promote spinal fusion. The Acme Spine System implants are intended to be used as a temporary construct that stabilizes the spinal operative site during fusion procedures and are not intended to replace normal body structures. The implants should be removed after fusion.

Materials:

All components of the Acme Spine System are made from implant grade Titanium Alloy (Ti 6Al 4V ELI) complying with ASTM F136. Materials for the instrumentation are made from ASTM stainless steels, and established medical grade plastics.

Intended Use:

When used as a posterior, pedicle screw system, The Acme Spine System is a pedicle screw system intended for patients with severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion mass.

The Acme Spine System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

Legally Marketed Predicate Device:

Aesculap, Inc. - Spine System Evolution

Substantial Equivalence:

The Acme Spine System components are substantially equivalent having similar design characteristics, i.e. materials, intended use, and method of implantation as the Aesculap, Inc. (K980484) Spine System Evolution legally distributed by Aesculap, Inc.

Performance Data:

Static and fatigue mechanical tests utilizing ASTM F1717 were performed on the Acme Spine System and demonstrate the comparable mechanical and endurance properties of these components with the long standing, basic design concepts of spinal implant devices.

Sterilization:

Acme Spine System components are provided nonsterile. High temperature steam autoclave sterilization should be used. The following cycle has been Hospital validated:

Method:	Steam
Cycle:	Gravity
Temperature:	250°F (121°C)
Exposure Time:	30 minutes

Conclusion:

The Acme Spine System is substantially equivalent to the compared predicate device in implantation technique, intended use, materials, design and function, testing standards, cautions and warnings.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 3 2000

Mr. Timothy Williams
Manager, Regulatory Affairs
ACME Spine LLC.
9980 Indiana Avenue, Unit 9
Riverside, California 92503

Re: K001044
Trade Name: ACME Spine System
Regulatory Class: II
Product Code: MNH, MNI
Dated: August 3, 2000
Received: August 7, 2000

Dear Mr. Williams:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N. Milken

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Ver/ 3 – 4/24/96

Applicant: ACME SPINE, LLC.

510(k) Number (if known): K001044

Device Name: ACME SPINE SYSTEM

Intended Use Statements:

1. **Spondylothesis Spinal Fixation Device System, (MNH) the intended use and indications for use are:**

The ACME Spine System is a pedicle screw system indicated for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

2. **Pedicle Screw Spinal System, (Class II uses) (MNI) the intended use and indications for use are:**

The ACME Spine System is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine:

Degenerative spondylolisthesis with objective evidence of neurological impairment,
Fracture,
Dislocation,
Scoliosis,
Kyphosis,
Spinal tumor, and
Failed previous fusion (pseudarthrosis)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Milhous

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001044

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional format 1-2-96)